IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETIC TECHNOLOGIES LIMITED,
an Australian corporation,

Plaintiff,

v. Civil Action No.

GENERAL GENETICS CORPORATION,
a Delaware corporation,

Defendant.

COMPLAINT WITH JURY DEMAND

Plaintiff Genetic Technologies Limited ("GTG") for its Complaint against Defendant General Genetics Corporation ("General Genetics"), alleges as follows:

I. THE PARTIES

1. Plaintiff GTG is an Australian corporation with a principal place of business in Victoria, Australia.

2. Upon information and belief, General Genetics is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 3655 Research Drive, Las Cruces, NM 88003. General Genetics can be served with process through its registered agent, the Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE, 19808.

II. JURISDICTION AND VENUE

3. This Court has exclusive jurisdiction of this action for patent infringement pursuant to 28 U.S.C. § 1338(a).

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

6. Upon information and belief, General Genetics has minimum contacts with this judicial district such that this forum is a fair and reasonable one. General Genetics has also transacted and/or, at the time of the filing of this Complaint, is transacting business within the District of Delaware. Further, upon information and belief, General Genetics has committed acts of patent infringement complained of herein within the District of Delaware, including the offering for sale infringing DNA testing services. For these reasons, personal jurisdiction exists over General Genetics and venue over this action is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

III. THE PATENT-IN-SUIT

7. On March 18, 1997, United States Patent No. 5,612,179 ("the '179 Patent") was duly and legally issued for an "Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes." A true and correct copy of the '179 Patent is attached as Exhibit A.

8. GTG is the owner of the '179 Patent by assignment from Genetype AG, who was originally assigned the technology by the inventor Dr. Malcolm Simons, with the exclusive right to enforce and collect damages for infringement of the '179 Patent during all relevant time periods.

9. The '179 Patent generally relates to methods of analysis of non-coding DNA sequences.

10. The Abstract of the '179 Patent relevantly provides:

> The present invention provides a method for detection of at least one allele of a genetic locus and can be used to provide direct determination of the haplotype. The method comprises amplifying genomic DNA with a primer pair that spans an intron sequence and defines a DNA sequence in genetic linkage with an allele to be detected. The primer-defined DNA sequence contains a sufficient number of intron sequence nucleotides to characterize the allele. Genomic DNA is amplified to produce an amplified DNA sequence characteristic of the allele. The amplified DNA sequence is analyzed to detect the presence of a genetic variation in the amplified DNA sequence such as a change in the length of the sequence, gain or loss of a restriction site or substitution of a nucleotide. The variation is characteristic of the allele to be detected and can be used to detect remote alleles.

11. Independent Claims 1 and 26 of the '179 Patent read:

> 1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising: a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and b) analyzing the amplified DNA sequence to detect the allele.
>
> 26. A DNA analysis method for determining coding region alleles of a multi-allelic genetic locus comprising identifying sequence polymorphisms characteristic of the alleles, wherein said sequence polymorphisms characteristic of the alleles are present in a non-coding region sequence, said non-coding region sequence being not more than about two kilobases in length.

12. The '179 Patent is presumed valid and enforceable pursuant to 35 U.S.C. § 282.

13. The '179 Patent was previously asserted by GTG in the matter of *Genetic Technologies Ltd. v. Applera Corp.*, Case No. C 03-1316-PJH, in the United States District for the Northern District of California ("Applera Action"). The Applera Action was ultimately settled with Applera Corporation taking a license to the '179 Patent, among others.

14. The '179 Patent was the subject of a declaratory judgment action initiated by Monsanto in the matter of *Monsanto Company v. Genetic Technologies Ltd.*, Case No. 06-cv-00989-HEA, in the United States District Court for the Eastern District of Missouri, Eastern Division ("Monsanto Action"). That Monsanto Action was ultimately settled. Monsanto has now taken three licenses to the '179 Patent, among others.

15. The '179 Patent was asserted by GTG in the matter of *Genetic Technologies Ltd. v. Beckman Coulter, Inc., et al*, Case No. 10-cv-0069-BBC, in the United States District Court for the Western District of Wisconsin ("Beckman Coulter Action"). The Beckman Coulter Action was resolved with at least Beckman Coulter, Inc., Gen-Probe, Inc., Interleukin Genetics Incorporated, Molecular Pathology Laboratory Network, Inc., Orchid Cellmark, Inc., Pioneer Hi-Bred International, Inc., and Sunrise Medical Laboratories, Inc. all taking a license to the '179 Patent, among others.

16. The '179 Patent was recently asserted by GTG in the matter of *Genetic Technologies Limited v. Agilent Technologies, Inc., et al*,. Case No. 11-cv-01389-WJM-KLM in the United States District Court for the District of Colorado ("Colorado Action"). In the Colorado Action at least Eurofins STA Laboratories, Inc. and GeneSeek, Inc. have taken a license to the '179 Patent, among others.

17. GTG has secured over $15 million in licensing revenue since the filing of the Beckman Coulter Action in 2010.

18. In addition to the licenses identified in the preceding paragraphs, the '179 Patent and related patents have been licensed to at least the following entities: AgResearch Ltd.; ARUP Laboratories, Inc.; Australian Genome Research Facility Ltd.; GeneDX (a subsidiary of Bio Reference Laboratories); Bionomics Ltd.; BioSearch Technologies Inc.; Pfizer Animal Health; C

Y O'Connor ERADE Village Foundation (incorporating the Immunogenetics Research Foundation and the Institute of Molecular Genetics and Immunology Incorporated); Crop and Food Research Ltd.; DNA Diagnostics Ltd.; General Electric Co. and its subsidiary GE Healthcare Bio-Sciences Corp.; Genosense Diagnostics GmbH; Genzyme Corp.; Innogenetics N.V.; Kimball Genetics, Inc.; Laboratory Corporation of America Holdings, Inc.; Livestock Improvement Corporation Ltd.; MetaMorphix, Inc.; Millennium Pharmaceuticals Inc.; Myriad Genetics, Inc.; Nanogen, Inc.; New Zealand Blood Service; Optigen, L.L.C.; Ovita Ltd.; Perlegen Sciences, Inc.; Prometheus Laboratories Inc.; Qiagen, LLC.; Quest Diagnostics Inc.; Sciona, Inc.; Sequenom, Inc.; Syngenta Crop Protection AG; Thermo Fisher Scientific Inc.; TIB MOLBIOL Syntheselabor GmbH; Tm Bioscience Corporation; Gen-Probe, Inc.; and others.

19. Certain claims of the '179 Patent, including Claim 26, were subjected to an ex parte reexamination before the United States Patent and Trademark Office ("USPTO") that was initiated by an unknown entity. On February 4, 2010, the USPTO issued a Notice of Intent to Issue Ex Parte Reexamination Certificate indicating that the subject claims were confirmed as valid without amendment. A true and correct copy of that Reexamination Certificate is attached as Exhibit B.

20. On May 10, 2012, a second ex parte reexamination of certain claims of the '179 Patent was requested by Merial Ltd. That ex parte reexamination request was granted on June 28, 2012. On September 26, 2012, the USPTO issued an Office Action indicating that Claims 2, 4-6, 10-12, 17 and 18 are confirmed as valid without amendment. A true and correct copy of the Office Action is attached as Exhibit C. Claims 1, 3, 7-9, 13-16 and 26-32 remain pending in the reexamination.

21. The '179 Patent expired on March 9, 2010. However, GTG remains entitled to collect damages for past infringement occurring during the term of the '179 Patent pursuant to 35 U.S.C. §§ 284 and 286. Specifically, for infringement occurring in the period commencing six years from the filing date of this Complaint through March 9, 2010.

IV. GENERAL GENETICS' INFRINGEMENT

22. General Genetics claims to have genetic, clinical, and forensic labs that provide comprehensive DNA testing services—including paternity, predisposition, and forensics testing—and clinically guided genetic analysis to people worldwide. Its marketing materials indicate that General Genetics has offices across the world and over 10,000 affiliate locations throughout North America, including in the District of Delaware.

23. Upon information and belief, General Genetics has analyzed many non-coding DNA polymorphisms linked to coding region alleles using amplified DNA with a primer pair spanning a non-coding DNA region in at least the provision of its paternity, forensic, amelogenin, and other DNA predisposition testing services during the term of the '179 Patent.

24. General Genetics' marketing materials state that it performs Autosomal Short Tandem Repeat ("STR") DNA analysis, Y-Chromosomal (i.e., Y-STR) DNA analysis, Mini STR DNA analysis, and Mitochondrial analysis, it offers both DNA screening and full sequencing services, and that it uses STR kits (specifically the PowerPlex 16 System (Promega)) to perform DNA amplification.

25. General Genetics has offered paternity DNA testing services during relevant time periods. Its marketing materials indicate that in the provision of these services, General Genetics tests sixteen genetic markers including thirteen markers referred to as the combined DNA Index System (CODIS), which are only used in the determination of human identity. Further, General

Genetics' marketing materials state that "15 different loci are examined for matches to the obligate paternal allele, as well as an additional match to confirm the sex of the person providing the sample."

26. General Genetics utilizes the PowerPlex 16 System (Promega) which employs 16 genetic markers, including amelogenin, to test paternity. Further, the Promega kits utilize the non-coding primer set targeting the 6 bp variation on the intron 1 of the amelogenin gene. Upon information and belief, the Powerplex kits used by General Genetics target the non-coding region to perform amplification and analysis of non-coding mutations of the amelogenin gene for gender identification, which infringed one or more claims of the '179 patent.

27. By way of example only, one of the genes that General Genetics tests is the amelogenin gene. Amelogenin (AMELX on the X chromosome and AMELY on the Y chromosome) is commonly used for gender identification (sex-typing) in conjunction with STR typing kits. Both AMELX and AMELY are multi-allelic genetic loci. AMELX carries a small deletion in the first intron, facilitating the design of amelogenin specific Polymerase Chain Reaction ("PCR") primers, enabling amplicons from the X-chromosome and Y-chromosome to be distinguished from one another when separation is performed, and allowing gender identification in humans. The DNA sequence being amplified is in an intron of the amelogenin gene and thus is an intrinsic part of the gene and is linked to the coding region allele.

28. General Genetics' has offered predisposition DNA testing services during relevant time periods. Its marketing materials indicate that the "concept of [its] genetic test is to look into your DNA and to identify key markers that, if present, may cause you to be predisposed to serious diseases." General Genetics' marketing materials state that it tests for twenty-five diseases and conditions including Alzheimer's disease, aneurysm, Celiac disease, colorectal

cancer, Graves' disease, lung cancer, Lupus, multiple sclerosis, obesity, osteoarthritis, peripheral vascular disease, psoriasis, rheumatoid arthritis, Type 1 diabetes, and Type 2 diabetes.

29. General Genetics' predisposition tests use non-coding polymorphisms, the majority of which are located in intron or intergenic (non-coding) regions in or near multi-allelic genes. For example, General Genetics' marketing materials indicate that it tests for Alzheimer's disease by looking for the single-nucleotide polymorphism ("SNP") marker rs4420638, which is located in an intergenic (non-coding) region near the multi-allelic APOC1 gene. General Genetics' marketing materials state that it tests for a predisposition to aneurysms by looking for the SNP marker rs700651, which is located in an intron (non-coding) region of the multi-allelic BOLL gene. Further, General Genetics' marketing materials explain that it tests for the following diseases and conditions by looking for these specific markers: Celiac disease for the SNP marker rs2187668 (located in an intron region of the multi-allelic HLA-DQA1 gene); colorectal cancer for the SNP markers rs12953717, rs4939827, and rs4464148 (located in intron regions of the multi-allelic SMAD7 gene); Graves' disease for the SNP markers rs1800630 and rs1800629 (located in intergenic regions near the multi-allelic TNF gene) and the SNP marker rs1799964 (located in an intergenic region near the multi-allelic LTA gene); lung cancer for the SNP marker rs951266 (located in an intron region of the multi-allelic CHRNA5 gene); Lupus for the SNP markers rs1800630 and rs1800629 (located in intergenic regions near the multi-allelic TNF gene), the SNP marker rs10488631 (located in an intergenic region near the multi-allelic TNPO3 gene), the SNP marker rs7574865 (located in an intron region of the multi-allelic STAT4 gene), the SNP marker rs9888739 (located in an intron region of the multi-allelic ITGAM gene), and the SNP marker rs2187668 (located in an intron region of the multi-allelic HLA-DQA1 gene); multiple sclerosis for the SNP marker rs12722489 (located in intron region of the multi-allelic

IL2RA gene) and the SNP marker rs3135388 (located in an intergenic region near the multi-allelic HLA-DRA gene); obesity for the SNP marker rs3764220 (located in an intergenic region near the multi-allelic SCG3 gene); osteoarthritis for the SNP marker rs4140564 (located in an intergenic region near the multi-allelic PTGS2 gene); peripheral vascular disease for the SNP marker rs951266 (located in an intron region of the multi-allelic CHRNA5 gene); psoriasis for the SNP marker rs1800629 (located in an intergenic region near the multi-allelic TNF gene); rheumatoid arthritis for the SNP marker rs3761847 (located in an intron region of the multi-allelic TRAF1 gene), the SNP marker rs7574865 (located in an intron region of the multi-allelic STAT4 gene), and the SNP marker rs3890745 (located in an intron region of the multi-allelic MMEL1 gene); type 1 diabetes for the SNP marker rs7574865 (located in an intron region of the multi-allelic STAT4 gene), the SNP marker rs3087243 (located in an intergenic region near the multi-allelic CTLA4 gene), and the SNP marker rs725613 (located in an intron region of the multi-allelic CLEC16A gene); and type 2 diabetes for the SNP marker rs10946398 (located in an intron region of the multi-allelic CDKAL1 gene), the SNP marker rs7903146 (located in an intron region of the multi-allelic TCF7L2 gene), the SNP marker rs4402960 (located in an intron region of the multi-allelic IGF2BP2 gene), and the SNP marker rs1111875 (located in an intergenic region near the multi-allelic HHEX gene). Upon information and belief, General Genetics performed amplification of non-coding regions of DNA and analyzed that amplified DNA to identify each of the foregoing markers to determine the associated predisposition, which infringed one or more claims of the '179 Patent.

30. Upon information and belief, General Genetics had actual knowledge of the '179 Patent during times relevant to this action through at least its awareness of GTG, the knowledge of its employees, and/or its research, development and/or patent application activities.

V. CLAIM FOR RELIEF
(Patent Infringement – U.S. Patent No. 5,612,179)

31. GTG incorporates by reference each and every allegation in paragraphs 1 through 30 as though fully set forth herein.

32. As described herein, General Genetics, itself, and/or by exercising direction and control over its subsidiaries, has manufactured, made, had made, used, practiced, imported, provided, supplied, distributed, sold, and/or offered for sale services that infringed one or more claims of the '179 Patent in violation of 35 U.S.C. § 271(a).

33. GTG has been damaged as a result of General Genetics' infringing conduct. General Genetics is thus liable to GTG in an amount that adequately compensates GTG for such infringement which cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

VI. JURY DEMAND

GTG hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

VII. PRAYER FOR RELIEF

GTG requests that the Court find in its favor and against General Genetics, and that the Court grant GTG the following relief:

A. Judgment that one or more claims of the '179 Patent has been directly infringed, either literally, and/or under the doctrine of equivalents, by General Genetics;

B. Judgment that General Genetics account for and pay to GTG all damages to and costs incurred by GTG because of General Genetics' infringing activities and other conduct complained of herein in an amount not less than a reasonable royalty;

C. That GTG be granted pre-judgment and post-judgment interest on the damages caused to it by reason of Defendant's infringing activities and other conduct complained of herein; and

D. That GTG be granted such other and further relief as the court may deem just and proper under the circumstances.

Dated: January 4, 2013

BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP

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